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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,069	11/27/2001	Cynthia C. Bamdad	M01015/70071 TJO/MJP	1136

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EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/996,069	BAMDAD ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-224* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-224* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to kit containing a peptide (MGFR) and candidate drug, classified in class 53, subclass 300.

II. Claims 4-9, drawn to method of screening useful compound using peptide, classified in class 435, subclass 4.

III. Claims10-30, drawn to method of treatment using an agent whose structure is not recited in the claim but has the function of inhibiting interaction of an activating ligand with a portion of a cell surface receptor that interacts with the activating ligand to promote cell proliferation, unclassifiable due to the undisclosed and/or unknown structure of the agent.

IV. Claims 31-40, drawn to method of treatment using an agent whose structure is not recited in the claim but has the function of preventing clustering of portions of cell surface receptors that interact with an activating ligand such as a growth factor to promote cell proliferation, unclassifiable due to the undisclosed and/or unknown structure of the agent.

V. Claims 41-46, 63-67, drawn to kit comprising a species able to become immobilized relative to a shed cell surface receptor, classified in class 530, subclass 387.1.

VI. Claims 47, drawn to a composition comprising at least a portion of a shed cell surface receptor interchain binding region and a signal entity, classified in class 530, subclass 350.

VII. Claims 48-67, drawn to kit comprising a species characterized as 17kD-35, or derived from 14-3-3, which binds to various cell surface receptor in addition to a signaling entity, classified in class 530, subclass 387.1.

VIII. Claims 68-85, drawn to peptide comprising at least a fragment of a sequence that corresponds to that portion of a cell surface receptor that

interacts with an activationg ligand and an affinity tag, classified in class 530, subclass 300.

IX. Claims 86 and 87, drawn to kit comprising a particle, a fragment of MUC1, classified in class 530, subclass 300.

X. Claims 88-106, drawn to kit comprising an article having a surface, a biomolecule, a second particle, a portion of a cell surface molecule, classified in class 530, subclass 350.

XI. Claim 107, drawn to method of exposing a ligand binding to a portion of a cell surface receptor, classified in class 434, subclass 4.

XII. Claim 108, drawn to method of exposing a portion of a cell surface receptor, classified in class 434, subclass 5.

XIII. Claims 109-112, drawn to method of exposing a synthetic drug, classified in class 435, subclass 4.

XIV. Claims 113-118, drawn to method of treating by administering fusaric acid, L-alpha-methyl-dopa, calcimycin, classified in class 514, subclass 354.

XV. Claims 119-124, drawn to method of treating by administering etomoxir, classified in class 514, subclass 233.8.

XVI. Claims 125-130, drawn to method of treating by administering L-alpha-methyl-dopa, classified in class 514, subclass 916.

XVII. Claims 131-136, drawn to method of treating by administering calcimycin, classified in class 514, subclass 449.

XVIII. Claims137-142, drawn to method of treating by administering butylindazole, classified in class 514, subclass 482.

XIX. Claims 143-148, drawn to method of treating by administering NS1619, classified in class 424, subclass 130.1.

XX. Claim 149, drawn to method of exposing any one of the Markush group species, and determine disruption of the interaction, classified in class 435, subclass 4.

XXI. Claim 150, drawn to method of treating by administering a compound without a structure identification, unclassifiable due to the unknown nature of the active ingredient.

XXII. Claims 151-157, drawn to method of treating with an agent that reduces cleavage of a cell surface receptor interchain binding region from the cell surface, unclassifiable due to the unknown nature of the active ingredient.

XXIII. Claims 158-184, 222, and 223, drawn to method of determining an amount of cleavage of a cell surface receptor, classified in class 435, subclass 7.1.

XXIV. Claims 185-186, drawn to method of determining a cleavage site, classified in class 435, subclass 7.1.

XXV. Claims 187, drawn to method of diagnosing a physiological state of cancer by determining a specific cleavage state of MUC1 distinguishable from a different cleavage state of MUC1, classified in class 435, subclass 7.23.

XXVI. Claims 188-208 and 224, drawn to method of first and second amount of determining cleavage of cell surface receptor, classified in class 435, subclass 4.

XXVII. Claims 209-217, drawn to method of diagnosing MUCI positive breast, prostate, lung, ovarian, colorectal, and/or brain cancer, and then treating, classified in class 435, subclass 7.23.

XXVIII. Claims 218, drawn to method of treating using an agent for inhibiting interaction of an activating ligand unclassifiable due to the unidentified structure of the agent.

XXIX. Claims 219, drawn to method of treating using an agent for inhibiting dimerization of a portion of a MUC1, unclassifiable due to the unidentified structure of the agent.

XXX. Claims 220, drawn to method of diagnosing MUC1 positive cancer by determining an amount of cleavage of a MUC1, classified in class 435, subclass 7.23.

XXXI. Claims 221, drawn to method of diagnosing, followed by treating using an agent for inhibiting dimerization of a portion of a MUC1, unclassifiable due to the unidentified structure of the agent.

The inventions are distinct, each from the other because of the following reasons:

Inventions II-IV and XI-XXXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to method requiring different active ingredients and active steps for different effects as stated in the preamble of the claims.

Inventions I, V-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to kits comprising different active ingredients.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species: protein 17KD, 23kD, 35kD, 14-3-3, cathespin D, NM23, annexin V, beta-lipotropin, proopiomelanocortin, etomoxir, calcimycin, fusaric acid, L-alpha-methyl-dopa, etomoxir, butylindazole. The species are independent or distinct because: each of the specifically claimed proteins or other chemical compounds are patentably distinct because the claimed agents have no substantial structural similarities, thus lack unity of invention. *In re Harnisch*, 631 F.2d 716, 206 USPQ 300(CCPA 1980); and *Ex parte*

Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Those claimed agents have no substantial structural similarities..

If any of the groups above recite any of the agents that lack unity of invention, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

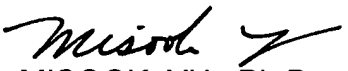
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does

not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 1642